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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 10/083,476 02/27/2002 Roger N. Piasio 4777 7590 10/01/2003 MARY HELEN SEARS EXAMINER The M.H. Sears Law Firm, Chartered DEVI, SARVAMANGALA J N 910 Seventeenth Street N.W. Washington, DC 20006 PAPER NUMBĘR ART UNIT 1645 DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

Applicant(s) 10/083,476

Piasio et al.

Office Action Summary Examiner

S. Devi, Ph.D.

Art Unit 1645



	The MAILING DATE of this communication appears of	n the cover s	heet with	the correspondence address	
	or Reply				
THE	ORTENED STATUTORY PERIOD FOR REPLY IS SET MAILING DATE OF THIS COMMUNICATION.	_			
	ions of time may be available under the provisions of 37 CFR 1.136 (a). In nate of this communication.	o event, however,	may a reply b	e timely filed after SIX (6) MONTHS from the	
- If the p	period for reply specified above is less than thirty (30) days, a reply within the				
- Failure - Any re	period for reply is specified above, the maximum statutory period will apply ar to reply within the set or extended period for reply will, by statute, cause the ply received by the Office later than three months after the mailing date of th	application to be	come ABANDO	NED (35 U.S.C. § 133).	
	patent term adjustment. See 37 CFR 1.704(b).				
Status 1) 💢	Responsive to communication(s) filed on <u>05/08/02</u>				
2a) 🗌	This action is <b>FINAL</b> . 2b)   ✓ This action	on is non-fin	al.		
3) 🗆	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.				
Disposi	tion of Claims				
4) 💢	Claim(s) <u>1-9</u>			js/are pending in the application.	
4	la) Of the above, claim(s)			is/are withdrawn from consideration.	
_	Claim(s)				
6) 🗆	Claim(s)			is/are rejected.	
7) 🗆	Claim(s)			is/are objected to.	
8) 🔯	Claims <u>1-9</u>	а	re subject	to restriction and/or election requirement.	
Applica	ition Papers				
9) 🗆	The specification is objected to by the Examiner.				
10)	The drawing(s) filed on is/are	a) 🗆 -accep	ted or b)[	$\Box$ objected to by the Examiner.	
_	Applicant may not request that any objection to the de	rawing(s) be I	neld in abe	yance. See 37 CFR 1.85(a).	
11)	The proposed drawing correction filed on	i	is: a) 🗌 a	approved b) $\square$ disapproved by the Examiner.	
	If approved, corrected drawings are required in reply t	o this Office	action.		
12)	The oath or declaration is objected to by the Exami	ner.			
Priority	under 35 U.S.C. §§ 119 and 120				
13)	Acknowledgement is made of a claim for foreign pr	iority under	35 U.S.C.	§-11.9(a)-(d) or (f).	
a)[	☐ All b)☐ Some* c)☐ None of:	*		Bernel Benen wassman gay, waa beesselse	
	1. ☐ Certified copies of the priority documents have			isto is establica de Santo de 1919, por l'illabatistica. L'	
	2.   Certified copies of the priority documents have	e been receiv	ved in Apr	olication No.	
	3. Copies of the certified copies of the priority do application from the International Burea	au (PCT Rule	17.2(a)).		
*S	ee the attached detailed Office action for a list of the	e certified co	pies not r	eceived.	
14)	Acknowledgement is made of a claim for domestic	priority unde	er 35 U.S.	C. § 119(e).	
a) [	The translation of the foreign language provisiona				
15)	Acknowledgement is made of a claim for domestic	priority unde	er 35 U.S.	C. §§ 120 and/or 121.	
Attachm		🗖 .	_		
_	otice of References Cited (PTO-892)			0-413) Paper No(s)	
_	otice of Draftsperson's Patent Drawing Review (PTO-948)		Informal Pater	rt Application (PTO-152)	
3) [_] Im	formation Disclosure Statement(s) (PTO-1449) Paper No(s).	6) Other:			

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## Restriction

- 1) Claims 1-9 are under prosecution.
- Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, drawn to an improvement in a bioassay for the detection of an antigen consisting of reducing the total amount of antibodies to an antigen, classified in class 435, subclass 7.1
  - II. Claim 9, drawn to an improvement in an immunochromatographic bioassay for the detection of an antigen consisting of removing excess of antigen by 'scrubbing', class 436, subclass 161 or 541
- 4) Inventions I and II are distinct from one another. Inventions I and II are drawn to two distinct methods which differ from one another in method steps/parameters and reagents or materials. Invention II requires the addition of an immovable 'scrub' to remove excess antigen whereas invention I reduces the total amount of antibodies without the requirement for a 'scrub'.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, restriction for examination purposes as indicated is proper.

- Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).
- Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER



## RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:
FROM/ATTORNEY:
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IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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